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Tyco Healthcare Group LP 60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473				
EXAMINER				
LEE, BENJAMIN HYOUNGSOI				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,666

Applicant(s)

CHAPMAN ET AL.

Examiner

BENJAMIN LEE

Art Unit

4137

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/1/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/04/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
- Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/22/06, 7/19/06, 6/12/06, 1/17/06,5/29/07, 12/13/07, 6/16/08 .

DETAILED ACTION

Claim Objections

1. Claims 1-2, 4, 6-7, 11-12 and 14 are objected to because of the following informalities: The term "insulative housing" does not specify whether the housing should be electrically insulative or thermally insulative, or generally insulative from the environment. Claims 2, 4, 6, 11, 12, 14 have the same issues. The term "insulative housing" will be interpreted to be electrically insulative housing for examination purposes. In claim 7, it recites the limitation "the electrically conductive sealing surface" in an electrode sealing assembly. There is insufficient antecedent basis for this limitation in the claim. However, base on the totality of Applicant's claimed invention, it would appear that the above limitation is referring to an electrically conductive sealing plate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 14 recites the limitation "the insulative housing" in an electrode sealing assembly. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claim 6 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 7,147,638 to *Chapman, et al.*. This is a double patenting rejection. Each of the limitations of claim 6 and its parent claim are met in claim 1 of U.S. Patent No. 7,147,638.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims are 1-5, 7-14 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 11, 1-2, respectively, of U.S. Patent No. 7,147,638 to *Chapman, et al.*.

As to claims 1-5 and 7-11, although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-10, respectively, of the reference meets all of the limitations of claim 1-5, 7-11 of the applicant and also includes lateral projections which extend from an outer periphery of the insulative housing of the thermally conductive, electrically non-conductive material of at least one of the first and second jaw members.

As to claim 12, although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the reference meets all of the limitations of claim 12 of the applicant and also includes a support step which extends relative to an upper surface of the insulative housing.

As to claims 13-14, although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2 of the reference meets all of the limitations of claim 13-14, respectively, of the applicant and also includes further limitations on the sealing plate (each plate having at least one corresponding electromechanical interface which mates with the electromechanical interface of the insulative housing) and also the thermally conductive electrically non-conductive

material (disposed between the insulative housing and the sealing plate, has lateral projections).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

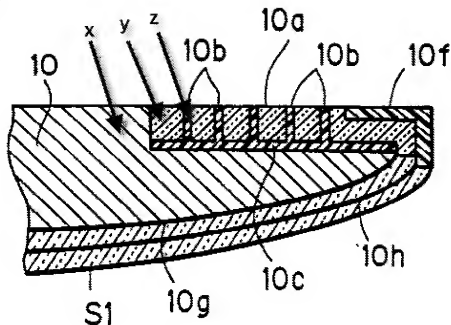
10. Claims 1-3, 8-9, 11, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,151,102 to *Kamiyama, et al.*, hereinafter *Kamiyama*.

As to claim 1, *Kamiyama* discloses an electrode sealing assembly comprising:

- first and second jaw members (1) each having an insulative housing. Note that the applicant does not positively indicate that an "insulative housing" is 100% electrically insulative. The housing consists of the blood vessel holding section 10 and insulation coating S1 which together house and electrically insulate the electrode assembly and are together called an insulative housing (Fig. 5).
- The jaws are movable from a first position in spaced relation relative to one another to at least one second position for grasping tissue therebetween, each of the jaw members including:

- an electrically conductive sealing plate (Fig. 5, 10b, 10c, col. 3, lines 7-20) having at least one corresponding electromechanical interface which mates with the electromechanical interface of the insulative housing. The term "electromechanical interface" was interpreted to be "of, or relating to, or being a mechanical process or device actuated or controlled electrically" as defined by Merriam-Webster. The inset on the portion of housing 10 that holds the sealing plate 10b-c is an electromechanical interface (related to a mechanical device controlled electrically since the sealing plate (10b, 10c) which is an electrode is seating on it) and the surface of the sealing plate is an electromechanical interface (related to a mechanical device controlled electrically). The two interfaces mate to each other given they are joined together at their respective interfaces (Fig. 5).
- a thermally conductive, electrically non-conductive material (labeled "y" in Fig. 5 below) (Fig. 5, 10a, col. 2, lines 56-58) disposed between the insulative housing (10 and S1) (labeled "x") and the electrically conductive sealing plate 10b-c (labeled "z"). The thermally conductive, electrically non-conductive material is configured to engage at least one side of the sealing plate 10b-c.

FIG. 5

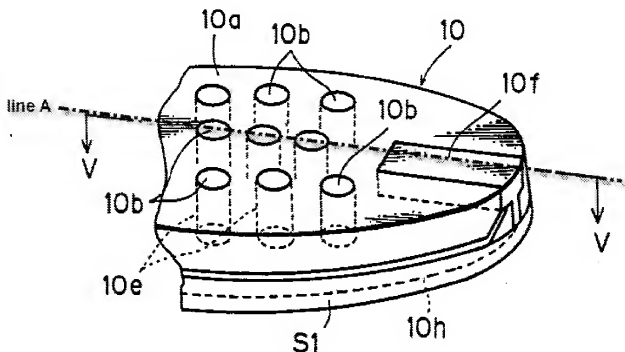


As to claim 2, *Kamiyama* discloses an electrode sealing assembly according to claim 1 where a thermally conductive, electrically non-conductive material (Fig. 5, 10a, col. 2, lines 56-58) secures and encapsulates the electrically conductive sealing surface 10b-c to the insulative housing (10 and S1). It is clear that the sealing surface electrodes 10b-c (labeled "z") are encapsulated by thermally conductive, electrically non-conductive material 10a (labeled "y").

As to claim 3, *Kamiyama* discloses an electrode sealing assembly according to claim 1 wherein the thermally conductive, electrically non-conductive material of at least one jaw member includes first and second segments which join to encapsulate the sealing plate. Applicant does not positively indicate that the two segments must have interfaces which join to encapsulate the sealing plate. Moreover, this claim also does

not require positively encapsulating completely the sealing plate. Line A on Fig. 4 below indicates an imaginary line through which the thermally conductive, electrically nonconductive material can be segmented and joined to encapsulate the sealing plates.

FIG. 4



As to claim 8, *Kamiyama* discloses an assembly according to claim 1 where the tissue contacting surfaces of the sealing plate 10b-c (labeled "z") and thermally conductive, electrically nonconductive material 10a (labeled "y") are substantially flush relative to one another (Fig. 5).

As to claim 9, *Kamiyama* discloses an electrode sealing assembly according to claim 1 wherein the jaw members are disposed at an angle relative to a shaft of the electrosurgical instrument (Fig. 1).

As to claim 11, *Kamiyama* discloses an electrode sealing assembly according to claim 1 wherein the insulative housing of at least one jaw member includes a support step which extends relative to an upper surface of the insulative housing and dimensioned to support the sealing plate. The portion of the insulative housing 10 extends relative to an upper surface of S1 of the insulative housing (10 and S1) and can be considered to be a support step that supports the sealing plate 10b-c.

As to claim 13, *Kamiyama* discloses every limitation of the electrode sealing assembly as shown above for claim 1.

As to claim 14, *Kamiyama* discloses an electrode sealing assembly according to claim 13 where a thermally conductive, electrically non-conductive material (Fig. 5, 10a, col. 2, lines 56-58) secures and encapsulates the electrically conductive sealing surface (Fig. 5, 10b, 10c) to the insulative housing (10). It is clear that the sealing surface electrodes (Fig. 4, 10b, 10c) are encapsulated by thermally conductive, electrically non-conductive material 10a.

11. Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,010,516 to *Hulka*.

As to claim 13, *Hulka* discloses an electrode assembly designed for use with an electrosurgical instrument for sealing tissue comprising first (Fig. 1, 12) and second (Fig. 1, 12) jaw members movable relative to each other with each jaw member including an electrically conductive sealing plate (Fig. 3, 22) and thermally conductive

electrically non-conductive material (Fig. 3, 26) configured to engage a side of the sealing plate.

As to claim 14, *Hulka* discloses an electrode assembly according to claim 13 wherein the thermally conductive electrically nonconductive material (Fig. 3, 26) encapsulates and secures the sealing plate (Fig. 3, 22) to the insulative housing (26 and 28). Note that the insulative housing was not defined to exclude the thermally conductive, electrically non conductive layer to be a part of the housing.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,151,102 to *Kamiyama* as applied to claim 1 above, PG Pub No. US 2003/0216733 A1 to *McClurken, et al.*

Kamiyama does not expressly disclose an electrode sealing assembly according to claim 1 wherein the insulative housing of at least one jaw member is made from a material selected from the group consisting of: nylon, syndiotactic-polystyrene, polybutylene terephthalate, polycarbonate, acrylonitrile butadiene styrene,

polyphthalamide, polyimide, polyethylene terephthalate, polyamide-imide, acrylic, polystyrene, polyether sulfone, aliphatic polyketone, acetal copolymer, polyurethane, nylon with polyphenylene-oxide dispersion and acrylonitrile styrene acrylate.

McClurken, drawn to a surgical device which is similar *Kamiyama's* device, teaches using a polymer coating as an electrically insulative coating (68) on the jaw of his coagulation device (Fig. 8, ¶ 90). He also teaches several types of polymers that can be used as electrically insulating materials on support members (58a-b) and base portions (60a-b) such as polyacetal (POM), polyamide (PA), polyamideimide (PAI), polyetheretherketone (PEEK), polyetherimide (PEI), polyethersulfone (PES), polyimide (PI), polyphenylenesulfide (PPS), polyphthalamide (PPA), polysulfone (PSO), polytetrafluoroethylene (PTFE) and syndiotactic polystyrene (SPS) (¶ 86).

It would have been obvious to one of ordinary skill in the art to utilize one of the multitude of polymers such as (for example) PA, PES, etc as disclosed *McClurken*, for insulative coating S1 on the device of *Kamiyama*, because one in the art would have chosen from among known effective electrically insulating coating materials in the art.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,151,102 to *Kamiyama* as applied to claim 1 above, in view of U.S. Patent No. 5,810,764 to *Eggers, et al.*, hereinafter *Eggers*.

As to claim 5, *Kamiyama* does not expressly disclose an electrode sealing assembly according to claim 1 wherein the thermally conductive, electrically non-conductive material of at least one jaw member is at least one of thermally conductive

plastic and anodized aluminum. *Eggers* teaches an electrosurgical instrument with active electrode surfaces that may be provided by assembling alternating layers of electrically conductive members (210) and electrically insulating spacers (Fig. 19, 320) which are made from either anodized aluminum, ceramic, glass, glass ceramic, or plastic (col. 11, lines 47-58). Fig. 19 clearly shows the insulating spacer (320) between each electrode (210) much like the electrode assembly of *Kamiyama*. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a thermally conductive, electrically non-conductive material of at least one jaw member to be at least one of thermally conductive plastic and anodized aluminum, given the various options for thermally conductive and electrically insulative materials which possess the desired properties of electrical insulation and thermal conduction.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over 5,151,102 to *Kamiyama, et al.* as applied to claim 1 above, in view of PG Pub No. US 2003/0216733 A1 to *McClurken, et al.*, hereinafter *McClurken*, in further view of U.S. Patent No. 6,178,628 to *Clemens, et al.*, hereinafter *Clemens*. As to claim 6, *Kamiyama* does not expressly disclose an electrode assembly according to claim 1 wherein the thermally conductive, electrically nonconductive material of at least one jaw member includes projections which extend laterally from an outer periphery of the insulative housing. However, *McClurken, drawn to a surgical device similar to the one taught by Kamiyama*, teaches that "it may be necessary to further increase the thermal conductivity of support members 58a, 58b and base portions 60a, 60b to better function

as heat sinks to remove heat transferred to surfaces 62a, 62b from tissue there between (¶ 90)". The heat sink support members are located between the electrodes as shown in Fig. 16. *Kamiyama's* device also places the thermally conductive electrically nonconductive material between the electrodes. Furthermore, *Clemens* discloses that "a typical heat sink for electrical applications functions by conducting heat away from the heat generating component and dissipating the heat into the surrounding air, heat sink are typically shaped to maximize surface area by incorporating fins or pins which increases the heat sink surface area" and increases "the physical size of the thermal interface between the heat sink and the surrounding atmosphere....thereby increasing the heat sink ability to dissipate heat to the surrounding atmosphere. (col. 2, lines 9-18)". It is clear that including fins on a thermally conductive material increases the material's ability to dissipate heat. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to have the thermally conductive, electrically nonconductive material of at least one jaw member include projections, or fins, which extend laterally in order to increase the surface area to best dissipate heat into the surrounding atmosphere because *McClurken* teaches a thermally conductive, electrically nonconductive material to behave as a heat sink in order to remove heat transferred to tissue contacting surfaces of his coagulation device (¶ 90).

16. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,151,102 to *Kamiyama, et al.* as applied to claim 1 above, in view of U.S. Patent No. 6,277,117 to *Tetzlaff, et al.*, hereinafter *Tetzlaff*.

As to claim 7, *Kamiyama* discloses an electrode sealing assembly with all the limitations of claim 1 as explained above. *Kamiyama* does not expressly disclose the added element of a stop member extending from at least one of the jaws. However, *Tetzlaff* teaches using a stop member (Fig. 7, 106) on the jaws of an electrode assembly on a forceps for vessel sealing. It would have been obvious to one of ordinary skill in the art at the time of the invention to have added a stop member extending from at least one of the jaws in order to restrict and/or regulate the movement of the electrodes relative to one another to achieve the desired gap range for optimal function of the device (col. 7, lines 50-60).

As to claim 10, *Kamiyama* does not expressly disclose an electrode sealing assembly according to claim 1 wherein the electrode sealing assembly is disposable. However, *Tetzlaff* discloses a disposable electrode assembly. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have made a disposable electrode sealing assembly in order to have an electrode assembly for a single use and eliminate the need for cleaning or sterilization (col. 9, lines 6-9).

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,151,102 to *Kamiyama, et al.* in view of U.S. Patent No. 6,277,117 to *Tetzlaff, et al.*, hereinafter *Tetzlaff*

As to claim 12, *The discussion of the Kamiyama patent in numbered paragraph 10 is incorporated herein.* *Kamiyama* discloses an electrode sealing assembly with all the limitations of claim 1 as explained above. *Kamiyama* does not expressly disclose

the added element of a stop member extending from at least one of the jaws. However, *Tetzlaff* teaches using a stop member (Fig. 7, 106) on the jaws. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have added a stop member extending from at least one of the jaws in order to restrict and/or regulate the movement of the electrodes relative to one another to achieve the desired gap range for optimal function of the device (col. 7, lines 50-60).

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L./ 4/20/2009
Examiner, Art Unit 4137

/Sam Chuan C. Yao/
Supervisory Patent Examiner, Art Unit 4111